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APPL. NO.	FILING DATE	APPLICANT	ATTORNEY DOCKET NO.
08/479,038	06/07/95	DROHAN	W 1327.0440006

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EXAMINER	
ZEMAN, M	
ART UNIT	PAPER NUMBER
1643	19

DATE MAILED: 05/22/98

Below is a communication from the EXAMINER in charge of this application

COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION

☒ THE PERIOD FOR RESPONSE:

a) ☒ is extended to run 3 or ~~continues to run~~ _____ from the date of the final rejection

b) ☐ expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition , and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☒ Appellant's Brief is due in accordance with 37 CFR 1.192(a).

☒ Applicant's response to the final rejection, filed 4/30/98 has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

1. ☒ The proposed amendments to the claim and /or specification will not be entered and the final rejection stands because:

   a. ☒ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.

   b. ☒ They raise new issues that would require further consideration and/or search. (See Note).

   c. ☒ They raise the issue of new matter. (See Note).

   d. ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

   e. ☐ They present additional claims without cancelling a corresponding number of finally rejected claims.

   NOTE: - See attached -

2. ☐ Newly proposed or amended claims _____ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.

3. ☒ Upon the filing an appeal, the proposed amendment ☐ will be entered ☒ will not be entered and the status of the claims will be as follows:

   Claims allowed: _____
   Claims objected to: _____
   Claims rejected: 12-20+24-33

   However;

   ☒ Applicant's response has overcome the following rejection(s): - See attached -

4. ☐ The affidavit, exhibit or request for reconsideration has been considered but does not overcome the rejection because _____

5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficent reasons why it was not earlier presented.

☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.

☐ Other

ADVISORY ACTION

1. Applicant's amendment after final rejection will not be entered, as it presents new grounds for consideration and search.

The proposed amendments to the claims raise the following new issues or new grounds of search:

Applicant introduces Fibrin matrices made using Fibrinopeptide A or Fibrinopeptide B. This is a new limitation, which would require further searching on this topic. Furthermore, it is not clear whether fibrinopeptides A and B are inherently part of a fibrin matrix, and no such inherency has been pointed out to the examiner. Additionally Applicant's amendment introduces new matter since the specification provides no support for claiming "fibrinopeptide A or fibrinopeptide B".

Applicant introduces the new condition that the supplement "retards the degradation of the matrix". No such limitation has been pending previously, nor is it clear that this phrase has clear written description in the specification as filed. None of the previously pending claims set forth this limitation, accordingly, a search would be required.

Applicant has broadened the scope of several claims from being used on tissues of a patient to an "environment of use" which could be other than that of a patient? This issue would require further searching.

Applicant has rearranged the types of supplements in the various independent claims, apparently randomly, and has added new species. There is no support set forth for such

rearrangement, and it would require searching to determine if the prior art discloses or teaches the newly submitted species. For instance, examination is required to determine where in the continuation applications there is support for each newly submitted species.

As to the rejections made under 35 U.S.C. 102 and 103, Applicant has not further defined or limited the metes and bounds of the "sustained release" limitation in the pending claims, nor has Applicant's "sustained release" preparations been sufficiently distinguished from those of the prior art, consequently the art rejections of record are maintained. Applicant continuously relies upon the argument that none of the art suggests that a supplement be incorporated at a level greater than it is soluble, but it would appear to be a routine optimization of known parameters to adjust the levels of a supplement depending on the dose desired, and the length of time one wished to have the supplement administered in the subject.

In regard to Cadoni et al. (Endoscopy 1990 22 p194-195) Applicant's arguments are not persuasive. Cadoni discloses a delivery system for administering an antibiotic slowly over several days. (see p 194, column 2, third full paragraph.) Whether further antibiotic solutions were used in Cadoni is not germane to the claims as currently pending, as the claims do not recite that methods for delivering supplements which exclude the use of other preparations.

Sakurai (J Cont. Release 1992 18 p39-44) discloses controlled release of an antibiotic from a fibrin matrix. The examiner notes on the record that Applicant admits that Sakurai is prior art against at least some of the pending claims.

Applicant attempts to predate Greco (J Biomed Materials 1991 25 p39-51) but does not submit evidence that Applicant's had reduced the invention to practice prior to the publication of Greco. The priority bring claimed is to an application filed in November, 1991. Greco was published in January of 1991.

Applicant attempts to predate Lontz (US Patent 5,420,250) however, Lontz also has priority under 35 U.S.C. 120 to applications filed in 1990. Applicant points to exemplary portions of the *present* specification to support its claim for priority. Lontz teaches the addition of glycoproteins, polysaccharides, and numerous other entities to the fibrin matrix for controlled release. At column 5 Lontz discusses some of the components "The associated plasma macromolecular proteins... characterized as glycoproteins... are intended to be retained as component portions of the {compositions)." The addition of other polysaccharides strengthen the fibrin matrix. Applicant has not indicated which species (ie polysaccharides) are entitled to the priority dates, including the new species, which include "cardiovascular drugs".

Applicant asserts that Stroetmann (US Patent 4,427,651)does not set forth the invention as claimed. Applicant's arguments are not persuasive as Stroetmann sets forth a composition comprising large quantities of powdered antibiotic and the components of a fibrin matrix that form said matrix upon application and liquification of the components.

Luck (US Patent 4,619,913) sets forth fibrin matrix compositions which specifically provide for formulations of controlled release of supplements. For example, see column 4 lines 37-55.

Wahlig (US Patent 4,853,225) sets forth fibrin matrix compositions specifically formed to offer delayed release of chemotherapeutics.

Applicant attempts to predate Juergensen (US Patent 5,549,904) however fails to point out where in the priority history of the application the addition of enzymes to fibrin matrices, such as those set forth by Juergensen, were introduced. Similarly, the rejection of Juergenson in view of Gerhart, and Juergensen in view of Opperman are maintained.

Applicant attempts to predate Marx (US Patent 5,607,694) which discloses the incorporation of liposome protected drugs into fibrin matrices for extended release of the drug. However, Applicant has not pointed out where in the prosecution history of the application that liposome incorporated bioactive agents were added.

2. The only rejections that have been overcome are the following:

a. The rejections made under 35 U.S.C. 112, first paragraph.

b. The rejection under 35 U.S.C. 103 as unpatentable over Weiner is withdrawn.

c. The rejection under 35 U.S.C. 102(b) over JP 60-204725 is withdrawn.

d. The rejection under 35 U.S.C. 102(e) over Khadem (US Patent 5,552,452) is withdrawn.

e. The rejection under 35 U.S.C. 102 (e) over Gristina (US Patent 5,505,945) is withdrawn.

f. The rejection under 35 U.S.C. 102(a) over WO 92/17206 is withdrawn.

3. All of the remaining rejections are upheld.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133. The examiner can be reached between the hours of 8:00 am and 5:30 pm Monday through Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marian Knode, can be reached on (703) 308-4311.

The fax number for this Art Unit is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

mkz
May 20, 1998

ANTHONY C. CAPUTA
PRIMARY EXAMINER